

## Altera Law Group, LLC

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## FAX TRANSMISSION COVER SHEET

FROM: Altera Law Group, LLC  
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December 12, 2003  
Page(s): 22PHONE NO.: 952-253-4100  
FAX NO.: 952-912-0574  
Fax No.: (703) 872-9306  
Phone No.: (703) 308-4018TO: Commissioner for Patents and  
Trademarks  
ATTN: Examiner Thomas Sweet  
Alexandria, VA 22313-1450

FROM: Hallie A. Finucane

OFFICIAL

Applicant: Woo, et al. Serial No.: 10/004504  
Filed: 10/26/2001 Group Art Unit: 3738  
Docket No.: 01610.0102-US-01  
Title: VALVED PROSTHESIS WITH POROUS SUBSTRATE

## Documents Transmitted:

This Fax Cover Sheet (1 page)

Amendment and Response Under 37 C.F.R. §1.111 (16 pages)

Declaration under 37 CFR §1.131 with Exhibit A (5 pages)

CLAIMS AS AMENDED					
	Claims Remaining After Amendment	Highest No. Previously Paid For	Extra Claims Present	Rate	Fees
Total Claims	39	39	0	X \$18.00	\$ 0
Indep. Claims	3	3	0	X \$86.00	\$ 0
Multiply Dependent Claims					\$ 0.00
					<b>TOTAL FEES</b> \$ 0

Please charge any fees or credit any overpayment to Deposit Account 50-1038.

Respectfully submitted,

Altera Law Group, LLC  
Customer No. 22865

Date: December 12, 2003

By: Hallie A. Finucane  
Hallie A. Finucane  
Reg. No. 33,172  
HAF/mar

I hereby certify that this paper is correspondence is being facsimile transmitted by facsimile to the U.S. Patent and Trademark Office, Fax Number (703) 872-9306 on December 12, 2003

Hallie A. Finucane  
Name of Person Signing Certificate

Signature

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Serial No. 10/004504

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Woo, et al. Examiner: Thomas Sweet  
Serial No.: 10/004,504 Group Art Unit: 3738  
Filed: October 26, 2001 Docket No.: 01610.0102-US-01  
Title: VALVE PROSTHESIS WITH POROUS SUBSTRATE

I hereby certify that this paper or correspondence is being transmitted by facsimile to the U.S. Patent and Trademark Office, Fax Number (703) 872-9306 on December 12, 2003.

By: Halle A. Finucane  
Halle A. Finucane

DECLARATION UNDER 37 C.F.R. § 1.131

Mail Stop Non-Fee Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

I, Yi-Ren Woo, declare and say as follows:

1. I am a named co-inventor of the subject matter of claims 1-38 in the above identified U.S. Patent Application, Serial No. 10/004504 filed October 26, 2001.
2. I have read and understood the Office Action mailed September 12, 2003, and make this Declaration in support of the patentability of the claims of U.S. Patent Application Serial No. 10/004504
3. I, Yi-Ren Woo, received a B.S. in chemical engineering from Chung Yaung University in Taiwan in 1975, and a M.S. in 1980 and a Ph.D in 1984., both in chemical engineering, from Georgia Institute of Technology. I joined St. Jude Medical, Inc., in St. Paul, Minnesota, in 1985 as a Senior Engineer followed by a Manager position in product support services from 1989 to 1991, and as a Technical Support Specialist from 1992 to 1993. From 1994 to 1995, I was a Manager, New Materials Development at Mentor in Dallas, Texas. I was employed as a Senior Engineer II at

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Alcon Laboratories in Fort Worth, Texas, from 1996-1997. From August 1997 to present, I have been employed at S. Jude Medical, Inc. as a Principal Engineer. I am listed as a co-inventor of three U.S. issued patents, and several U.S. pending patent applications, all relating to heart valves, and have authored / co-authored more than 20 publications and 15 presentations.

4. Prior to June 14, 2001, the publication date of international application WO 01/41825 to Carlyle et al, cited by the Examiner in the Office Action mailed on September 12, 2003, and upon which the rejection of claims 1-3, 5-15, and 18-23 is based, we conceived of the invention as presently claimed in claims 1-39.

5. As factual evidence of the conception of the claimed invention prior to June 14, 2001, attached hereto as Exhibit A and incorporated herein by reference, is a copy of an invention disclosure, which is signed by each of us and dated prior to June 14, 2001. The invention disclosure was witnessed and understood by Matt Ogle and Chad Cai, employees at St. Jude Medical, Inc., also prior to June 14, 2001.

6. The invention disclosure discloses a mechanical heart valve employing a rigid polymeric, ceramic, and/or metallic material for the occluder(s). Polymeric material is preferred to minimize impact loading at the valve closure. The occluder material should be porous with appropriate pore size that allows tissue growth. The pores can contain chemical and/or biomolecules that attract cells and promote tissue growth. The chemicals and/or biomolecules may also be incorporated into hydrogels to control release of the chemicals and/or biomolecules. The hydrogels, when used, can fill the pores and provide a smooth flow surface to the occluder(s), though the surface of the occluder(s) can possess certain macroscopic topographical features to encourage and/or modulate cell attachment and proliferation. Endothelial cell growth is expected on the occluder(s) after implantation. The porous material can also be used to construct the housing of the valve to make the entire surface non-thrombogenic.

7. After conceiving of the invention, due diligence was continuously exercised in developing the invention, including presenting the invention to management for consideration for submitting a patent application. On information and belief, after passing through standard company procedures, a decision was made to apply for a

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U.S. Patent on the invention. Consequently, U.S. Patent Application Serial No. 10/004,504 was filed on October 26,2001.

8. The foregoing statements are made of my own knowledge and are true except for those indicated as being made on information and belief, and as to them I believe them to be true. I hereby acknowledge that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. § 1001) and may jeopardize any validity of Application Serial No. 09/459,451 or any patent issuing thereon.

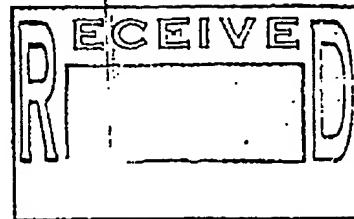
Yi-Ren Woo

Dated this 12 day of December, 2003

Yi-Ren Woo



Exhibit A



## INVENTION DISCLOSURE

DOCKET NUMBER: \_\_\_\_\_

DATE RECEIVED: \_\_\_\_\_

RECEIVED BY: \_\_\_\_\_

(Fill out, sign, have witnessed and send to St. Jude Medical Patent Department as soon as you have made an invention. If you have any questions, consult the Patent Department.)

1. TITLE OF INVENTION: Prosthetic Heart Valve Using Porous Materials

## 2. PROBLEM TO BE SOLVED: Briefly describe the purpose or problem your invention is trying to solve, and/or any background or state-of-the-art information.

The mechanical valve recipients need to be on anticoagulation therapy due to the flow disturbances that the valve structure produce and the inadequate blood compatibility of the material used to construct the valve.

## 3. DESCRIPTION OF THE INVENTION: Provide a complete and concise description of your invention. The description should include (to the extent known at the time of this disclosure): the nature, structure, operation, and physical, chemical, biological, or electrical characteristics, with sketches and/or schematic diagrams where possible. List the novel features and advantages. Identify the number of sheets attached which form a part of the disclosure (if any): pages.

A mechanical heart valve employs a rigid polymeric, ceramic, and /or metalic material for the occluder(s). If a polymeric material is chosen, the impact loading at valve closure can be minimized. The occluder material shall be porous with appropriate pore size that allows tissue ingrowth. The inside surface of the pore can be coated with appropriate chemicals and/or biomolecules that attract cells and encourage tissue ingrowth. The chemicals and biomolecules may also be incorporated into a hydrogel material that further controls the release of the chemicals and biomolecules. When a hydrogel is used, the hydrogel will fill the pore and provide the occluder a macroscopically smooth surface to the flow. However, the surface of the occluder may possess certain microscopic topographical features that encourages and /or modulates cell attachment and proliferation. It is expected that such an occluder will be endothelialized after implantation and therefore, have the most non-thrombogenic surface.

Such a porous material can also be used to construct the housing of the valve to make the entire valve surface non-thrombogenic.

## 4. PLANNED USES OF THE INVENTION: Identify any and all projects which will be incorporating this invention and provide the approximate date it is expected to be submitted to the FDA. The Patent Department should be kept apprised of any changes in status as soon as possible.

New generation heart valve.

New generation heart valve..

5. Has there been any publication, sale or public use, or disclosure of this invention to anyone outside of St. Jude Medical? YES    NO  X  

If "YES", complete the following, as appropriate:

5a. Title and date of publication \_\_\_\_\_

5b. Date of first sale \_\_\_\_\_

5c. Date of first public use \_\_\_\_\_

6. Are you aware of any technical papers, writings, patent application, or similar disclosure describing this invention? YES    NO  X  

If "YES", complete the following, as appropriate:

6a. Has the manuscript been accepted for publication at the time of the disclosure? \_\_\_\_\_

YES    NO   

6b. Type of document and title \_\_\_\_\_

6c. Document submitted to \_\_\_\_\_

6d. Anticipated publication or presentation date \_\_\_\_\_

**IDENTIFICATION OF CONTRIBUTOR(S):** Please list each person who has contributed to the conception of the invention.

1. Name Yi-Ren Woo \_\_\_\_\_ Tel. Ext. 7399 \_\_\_\_\_ Citizenship USA  
(Type or print in full)

Residence <u>873 Lake Ridge Alcove</u> Street	Woodbury City	Washington County	MN	55125
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Signature Yi-Ren Woo \_\_\_\_\_ Date \_\_\_\_\_

2. Name Abhay Pandit \_\_\_\_\_ Tel. Ext. 7675 \_\_\_\_\_ Citizenship India  
(Type or print in full)

Residence <u>3641 Harriet Ave</u> Street	Minneapolis City	Hennepin County	MN	55009
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Signature Abhay Pandit \_\_\_\_\_ Date \_\_\_\_\_

**IN WITNESSES:** I have read and understood the attached invention, and/or the invention has been explained to me.

Signature of Witness Murat G. Ge \_\_\_\_\_ Date \_\_\_\_\_

Signature of Witness Abhay Pandit \_\_\_\_\_ Date \_\_\_\_\_